5. 510(k) Summary

JUN 14 2013

Date Prepared:

February 5, 2013

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, Connecticut 06902

Telephone: (301) 251-1092
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Contact: Jyh-Shyan Lin

Device Trade Name:

Synapse 3D Lung and Abdomen Analysis

Device Common Name:

Medical Image Processing and Analysis Software

Regulation Number:

21 CFR 892.2050

Device Classification:

Class II

Device Classification Name:

Picture Archiving and Communications System (PACS)

Panel:

Radiology

Product Code:

LLZ

Date Received:

TBD

Decision Date:

TBD

Decision:

TBD

Predicate Device:

- Synapse 3D Lung and Abdomen Analysis (K120648), FUJIFILM Medical Systems U.S.A., Inc.
- Pulmonary Workstation 2 (K083227), VIDA Diagnostics, Inc.

Description of the Device

Synapse 3D Lung and Abdomen Analysis is the updated version of previously-cleared Synapse 3D Lung and Abdomen Analysis software (cleared by CDRH via K120648 on 06/14/2012).

Synapse 3D Lung and Abdomen Analysis is used in addition to Synapse 3D Base Tools (K120361) to analyze the images acquired from CT. Synapse 3D Lung and Abdomen Analysis is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning of DICOM compliant medical images.

Synapse 3D Lung and Abdomen Analysis is an application that performs the CT lung analysis/airway, lung analysis scope, and abdomen 2D and 3D fat analysis.

Unchanged Applications from the cleared version K120648

(1) Lung analysis/Airway is an application using non-contrast and contrast enhanced computed tomographic images of the lung which provides custom workflows and UI, and reporting functions including boundary detection and volume calculation for pulmonary nodules in the lung based on the location specified by the user, segmentation of bronchial tubes in the lung, approximation of air supply region by the user specified bronchial tube, identifying, displaying and processing low absorption regions in the lung.

Unchanged Applications from the cleared version K103720

(1) 2D Fat Analysis is an application which can use single slice (2-dimensional) non-contrasted CT images to calculate subcutaneous fat and visceral fat areas.
(2) 3D Fat Analysis is an application which can use volume (3-dimensional) non-contrasted CT images to calculate subcutaneous fat and visceral fat areas and volumes.

New application in this submission

(1) Lung Analysis Scope is an application using non-contrast and contrast enhanced computed tomographic images of the lung for searching an optimum bronchus path to reach a lung nodule by using the volume data collected with CT, and simulate insertion of bronchoscope into the path.

The following common image processing functions are available to support the analysis of the lung and abdomen CT images. These functions belong to and are provided by Synapse 3D Base Tools (K120361) that is used with Synapse 3D Lung and Abdomen Analysis (this submission).

- Window width and window level.
- Zooming, panning, flip, rotate.
- Measurement of lengths, areas, etc.
- Adding annotations on an image.

- Extraction and Deletion of 3D objects: Editing of mask areas using the smart cut feature.
- 3D clipping: The display area can be specified for 3D display.
- Creation of video files: Video files with 2D or 3D display can be created.

Indication for Use

Synapse 3D Lung and Abdomen Analysis is medical imaging software used with Synapse 3D Base Tools that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Lung and Abdomen Analysis accepts DICOM compliant medical images acquired from CT.
This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

Addition to Synapse 3D Base Tools, Synapse 3D Lung and Abdomen Analysis is intended to;

- use non-contrast and contrast enhanced computed tomographic images of the lung, provide custom workflows and UI, and reporting functions for lung analysis including boundary detection and volume calculation for pulmonary nodules in the lung based on the location specified by the user, segmentation of bronchial tubes in the lung, approximation of air supply region by the user specified bronchial tube, identifying, displaying and processing low absorption regions in the lung.
- use non-contrasted CT images and calculate subcutaneous fat and visceral fat areas in 2D and both volumes in 3D.
- analyze a bronchus path to reach a lung nodule using the volume data collected with CT, and simulate insertion of bronchoscope into the path.

Technological Characteristics

The proposed Synapse 3D Lung and Abdomen Analysis and the predicate devices, Synapse 3D Lung and Abdomen Analysis (K120648) and Pulmonary Workstation 2 (K083227), are medical application software running on Windows operating system installed on commercial general-purpose Windows-compatible computers. These devices are connected to CT with DICOM standard and retrieve image data via network communications. These devices provide 3D image visualization and manipulation tools for medical images with various user interfaces and measurement tools for analysis of rendered images. Both the Synapse 3D Lung and Abdomen Analysis and the predicate devices support the workflows, UI, and reporting functions for lung analysis/airway and lung analysis scope.

Synapse 3D Lung and Abdomen Analysis introduces no new safety or efficacy issues other than those already indentified with the predicate devices. The results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the device is of moderate concern as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices."

Testing

Synapse 3D Lung and Abdomen Analysis is tested successfully with reference to its Software Requirements Specification, as well as design verification and validation documents and Traceability Matrix document. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the Synapse 3D Lung and Abdomen Analysis software, which is found to be safe and effective and substantially equivalent to the currently-cleared predicate devices.

Testing involved system level functionality test, segmentation accuracy test, measurement accuracy test, interfacing test, usability test, serviceability test, labeling test, as well as the test for risk mitigation method analyzed and implemented in the risk management process. In addition, we conducted the bench performance testing using actual clinical images to help demonstrate that the proposed device achieved the expected accuracy performance.

Pass/Fail criteria were based on the requirements and intended use of the product. Test results showed that all tests successfully passed.

Conclusion

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject device to be as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 14, 2013

FUJIFILM Medical Systems U.S.A., Inc.
% Jyh-Shyan (Jesse) Lin, Ph.D.
Senior Manager, Regulatory, Quality and Clinical Affairs
419 West Avenue
STAMFORD CT 06902

Re: K130542
Trade/Device Name: Synapse 3D Lung and Abdomen Analysis
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 21, 2013
Received: March 22, 2013

Dear Dr. Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number:K130542

Device Name: Synapse 3D Lung and Abdomen Analysis

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- use non-contrasted CT images and calculate subcutaneous fat and visceral fat areas in 2D and both volumes in 3D.

- analyze a bronchus path to reach a lung nodule using the volume data collected with CT, and simulate insertion of bronchoscope into the path.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130542